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EXAMINER	
MARVICH, MARIA	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/559,583	Applicant(s) SCHLEPER ET AL.	
	Examiner MARIA B. MARVICH	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *6/30/10*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,8,9,11-15 and 20* is/are rejected.

7)☒ Claim(s) *5, 7, 10, 16-19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 June 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to an amendment filed 6/30/10. Claims 1-20 are pending in this application. However, claims 5-20 have been withdrawn from consideration as they are improper multiple dependent claims as they depend from another multiple dependent claim or depend from claims that depend from multiple dependent claims. See MPEP § 608.01(n). Should applicants amend the claims, consideration will be made as to which claims read on the examined subject matter. Claims 1-4 are under examination.

Applicants' amendment to add SEQ ID NO:s to the listings on page 14 and 15 are sufficient to place the application in sequence compliance. Acknowledgement is made of substitute drawings which overcome the objections to the drawings.

The substitute oath is sufficient to overcome the objections to the oath.

Claim Objections

Claims 1, 2 and 4 objected to because of the following informalities: **These are new objections.**

It was recommended that Claim 1 step (b) recite that the vector comprises "coding sequences for structural proteins, a coding sequences for the site-specific integrase and a packaging signal from one of SSV1, SSV2 or pSSVx". However, upon reconsideration ,the step sets forth only that the packaging signal is from SSV1, SSV2 or pSSVx. It appears as if applicants intend that all 3 components are from SSV1, SSV2 or pSSVx which provides proper antecedent basis for "the site-specific integrase". Hence, it would be remedial to recite --coding sequences for structural proteins, a coding sequences for a site-specific integrase and a packaging signal wherein each of the structural coding sequences, the integrase coding sequences and the

packaging signal are from one of SSV1, SSV2 or pSSVx and are operably linked to expression control sequences--. Alternatively, as the packaging signal may not technically be linked to the expression control sequences, it would be remedial to recite, --coding sequences for structural proteins, a coding sequences for a site-specific integrase and a packaging signal wherein each of the structural coding sequences, the integrase coding sequences and the packaging signal are from one of SSV1, SSV2 or pSSVx and the structural coding sequences, the integrase coding sequences are operably linked to expression control sequences--. Applicants have stated that the components are operably linked to the packaging signal but it is not clear that this is necessary as the packaging signal is in the vector and according to the specification page 4 this is all that is required for function of the signal.

The phrase “de novo” in claim 4 should be italicized.

For clearer antecedent basis, claim 4 should recite --the essential protein-- or --the one or more selectable marker genes-- as opposed to “the essential gene”.

These are new objections necessitated by applicants' amendment. Claim2 recites ‘the coding sequence” whereas claim 12 refers to several. Claim 2 should indicate which one of the coding sequence is being referenced. It appears as if --wherein one of the structural proteins is an origin of replication from--.

Hence, in claim 3 the reference to “said origin of replication” does not indicate which of the two are recited. As well, when referring to previous limitations, the word "said" is used when the reference uses the terms as previously recited in exact terms. In this case, "said" is used improperly in claim 3 when referring to "said genes encoding the structural proteins".

Claim 5 should be amended to correct several minor informalities.

"The expression vector of anyone of claim 1, wherein the vector contains orotidine-5'-monophosphatase pyrophosphorlyase and orotidine-5'-monophosphatase decarboxylase as selectable marker genes". The phrase "anyone of" is improper as there is only one choice. For more direct antecedent basis, line 1 should recite, --wherein the essential protein is orotidine-5'-monophosphatase pyrophosphorlyase and orotidine-5'-monophosphatase decarboxylase--.

Claim 8 recites that the promote is selected from a group consisting of genes. This is an incorrect correlation as the promoter may be from genes but is not themselves the genes. For example, -- the promoter is a promoter from a gene selected from --. The formatting is further confused by reciting after a list of genes "including the promoters". Finally, the listing is improper in that the groups are recited as if the promoters are all of the promoters from 16S, 23S rRNA or all of those form polymerases, transcription, replication or translation factors. Correction should be made to refer to listings in the alternative only and to refer properly to either promoters of genes or promoters.

Claim 10, similarly, refers to listings in a manner that makes the choices unclear. It would be clearer to recite, --wherein the inducible promoter is selected from the group consisting of a heat inducible promoter selected from the group of promoters from Tf55alpha, TF55beta, TF55gamma, hsp20 or htrA, the cold inducible promoter from TF55gamma and a promoter inducible by a carbon source--.

Claim 11 recites "a reporter proteins" which is grammatically incorrect.

Claim 13 for consistency should recite --the marker for selection--. There are two markers and by referring more accurately to that in claim 12 it is clearer to which claim 13 refers.

Claim 15 is unclear. Claim 15 recites that "the transformed expression vector provides a gene encoding an essential protein". It is unclear if this is the same essential protein as that in claim 1. If so then the claim is redundant as claim 1 already recites that the gene is in the vector. As well, it is not clear how a vector can "provide" a gene. If it is the same as that in claim 1, claim 15 should be deleted. If it is an additional gene than the claim should be amended to recite --wherein the expression vector of claim 14 has an gene encoding a second essential protein--.

In claim 17 the phrase "(poly)peptide" is inconsistent with previous recitations.

Claim 18 as written has several informalities. The method is to generating infectious recombinant subviral particles composed of the structural proteins of an SSVI and/or an SSV2". The phrase "having packaged the DNA of the expression vector of claim 1" is unclear. It appears as if the particle comprises particle composed of SSV1 and/or SSV2 --and comprises the expression vector of claim 1--. Claim 1 does not refer to a DNA of the expression vector and hence this complicates the method. The particle is made by introducing --the expression vector and the SSV1 and/or the SSV1 into a host cell--. SSV1 and SSV2 here refer to those components which provide the structure. To make this clear use of the article "the" indicates that these are the same. As well, the preamble recites and/or but step a did not. Finally "a host cells" is grammatically incorrect. The phrase "incubating the cells for time and under conditions sufficient to allow replication of SSV1 or SSV2 and spreading in the cell culture" is tedious and is preferable as --incubating the cells under conditions sufficient to allow replication of SSV1 and/or SSV2--. Finally, the last step does not provide insight on how the preamble goals are met.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitation "the translation initiation site" in claim 1. There is insufficient antecedent basis for this limitation in the claim. There is no gene of interest in the vector hence there can be no translation initiation site. Rather there is a site for insertion of a gene of interest.

Claim 19 provides for the use of the vector of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 19 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). The claim appears to intend that the method is expressing the an RNAi or antisense. However, claim 1 does not include such sequences. And the recitation of a promoter for transcription of a gene or parts of a gene does not explicitly

require these sequences. Also the recitation that the vector contains a *Sulfolobus* promoter is redundant as the vector already contains such a promoter.

Response to Amendment.

Applicants' arguments have been considered but are not persuasive for the following reasons. Applicants argue that the 101 does not stand and that Stedman et al does not disclose genes encoding an essential protein for Sufolobus as these proteins are from SSV1 virus. By applicants' arguments, it appears as if the following limitations

- a sulfolobus origin of replication;
- one or more selectable marker gene(s) encoding an essential protein of sulfolobus, operatively linked to sulfolobus expression control sequences; and
- a sulfolobus promoter followed 3' by a restriction enzyme recognition

are intended to comprise components from Sulfolobus wherein this notation is limited to reference to "the hyperthermophilic Archaeon genera *Sulfolobus and* comprises the species *Sulfolobus acidocaldarius, Sulfolobus brierleyi, Sulfolobus hakonensis, Sulfolobus metallicus, Sulfolobus shibatae, Sulfolobus solfataricus.*" However, this interpretation is based upon limitations that are not explicitly required of the claims. To the contrary, the specification provides this description of SSV1 and SSV2 "[0009] The terms ".SSV1" and "SSV2" refer to types 1 and 2 of *Sulfolobus shibatae*, a circular double stranded DNA virus adapted to Sulfolobus." Hence, the recitation of an essential protein of sulfolobus, a sulfolobus origin of replication and a sulfolobus promoter does not as set forth by the specification occlude those from SSV1 and SSV2. While one could interpret the claim to encompass a situation in which

each of the essential protein of *Sulfolobus*, a *Sulfolobus* origin of replication and a *Sulfolobus* promoter are components encoded by the archean *Sulfolobus* genome, the claim language is so broad as to read on additional embodiments such as promoters, origins and protein. "While it is appropriate to use the specification to determine what applicant intends a term to mean, a positive limitation from the specification cannot be read into a claim that does not itself impose that limitation. A broad interpretation of a claim by USPTO personnel will reduce the possibility that the claim, when issued, will be interpreted more broadly than is justified or intended. An applicant can always amend a claim during prosecution to better reflect the intended scope of the claim." MPEP 2105. In this case, applicants claim language does not direct one to a single interpretation wherein the sulfolobus origin of replication, one or more selectable marker gene(s) encoding an essential protein of sulfolobus, operatively linked to sulfolobus expression control sequences; and a sulfolobus promoter followed 3' by a restriction enzyme recognition are limited to those isolated from the genome of an archean organism. In fact, the specification teaches

> [0014] The plasmid pSSVx is defined as a hybrid between a plasmid and a fusellovirus. This plasmid, in the presence of a helper (SSV1 or SSV2) is able to spread as a virus satellite via virus-like particles. Like pRN1 and pRN2, pSSVx belongs to the pRN family of Sulfolobus plasmids, as judged by its genome organization, by the high sequence similarity of a cluster of ORFs and two putative replication origins that comprise 50%-70% of their genomes. However, a tandem array of two ORFs in a non-conserved region in pSSVx is clearly homologous to a similar tandem of ORFs of as yet unknown function in SSV2 and SSV1, suggesting a viral origin for these plasmid ORFs. The plasmids pRN1 and pRN2, which lack these ORFs, do not spread with the help of SSV1 or SSV2, indicating that a sequence element in this cluster is for the packaging and spreading of pSSVx.

In other words, these plasmids have genes essential for sulfolobus.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. **This rejection is maintained for reasons of record in the office action mailed 2/3/10 and restated below.** The claims, as written, do not sufficiently distinguish over cells that exist naturally because the claims do not particularly point out any non-naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206, USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor , e.g. by insertion of "Isolated" or "Purified" . Specifically, the vector of claims 1-4 reads on natural SSV1, SSV2, pSSVx and pRN.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 8, 9, 11-15 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Stedman et al Genetics **152:** 1397–1405 (August 1999). **This rejection is maintained for**

reasons of record in the office action mailed 2/3/10 and restated below. The rejection is extended to newly examined claims 6, 8, 9, 11-15 and 20.

Stedman et al teach a vector that comprises the SSV1 genome and hence inherently comprises each of an ori, genes encoding the structural proteins and site-specific integrase from SSV1 each operably linked to expression control sequences. As well, the vector comprise essential genes encoding for example aminoacid biosynthesis genes (see figure 1). Furthermore, the vector has been modified with restriction sites that are flanked by expression control sequences of for example e178 (see figure 5). However, the vector will have natural restriction sites that are found within range of natural promoters. SSV1 comprises a number of promoters for example Tind is inducible by IV irradiation (see e.g. 1401, col 1, ¶ 2). However a number of the promoters (see e.g. figure 5) are constitutive. In figure 5 is a shuttle vector that further comprises an E. coli origin of replication as well as a variant of a reporter gene and a marker.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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